without subsidies and substantially reduce protections for those with preexisting conditions. The end result would be a shaky market dominated by health plans that offer limited coverage and high cost sharing.

Whereas Price’s actions to date have not reflected the tradition of the physician as advocate for the poor and vulnerable, they do harken back to an earlier tradition in American medicine: the physician advocate as protector of the guild. His Empowering Patients First Act would directly advance physicians’ economic interests by permitting them to bill Medicare patients for amounts above those covered by the Medicare fee schedule and allowing them to join together and negotiate with insurance carriers without violating antitrust statutes. Both these provisions would increase physicians’ incomes at the expense of patients. Price has consistently fought strategies for value-based purchasing and guideline development, opposing the use of bundled payments for lower-extremity joint replacements and proposing that physician specialty societies hold veto power over the release of comparative effectiveness findings. These positions reduce regulatory burdens on physicians at the cost of increased inefficiency and reduced quality of care — and reflect a striking departure from the ethos of his physician predecessors, Secretaries Bowen and Sullivan.

The HHS Department oversees a broad set of health programs that touch about half of all Americans. Over five decades and the administrations of nine presidents, both Democratic and Republican secretaries have used these programs to protect the most vulnerable Americans. The proposed nomination of Tom Price to HHS highlights a sharp contrast between this tradition of compassionate leadership and the priorities of the incoming administration.

**Disclosure forms provided by the authors are available at NEJM.org.**

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**Patient-Reported Outcomes — Harnessing Patients’ Voices to Improve Clinical Care**

Ethan Basch, M.D.

Symptom management is a cornerstone of clinical care, particularly for patients with chronic conditions. Yet patients’ symptoms and physical impairments go undetected by health care providers as much as half the time, particularly between clinic visits. As a result, we miss opportunities to intervene and alleviate suffering. Moreover, incomplete documentation of this information in the electronic health record (EHR) limits our ability to understand key patient outcomes when we aggregate EHR data for comparative effectiveness research or quality-of-care assessments.

Recent advances in technology and survey methods provide a potential solution in the form of patient-reported outcomes (PROs) recorded electronically — using simple but methodologically robust questionnaires, completed by patients at or between visits over the Internet or on a smart device, with data transmitted into the EHR. Clinicians can receive automated notifications about worrisome symptoms or functional issues, such as severe dyspnea or reduced physical activity in an outpatient with heart failure. They can review longitudinal PRO reports at visits and import that information into their EHR notes as part of the review of systems. There is evidence that this approach can improve patients’ quality of life, enhance patient–clinician communication, reduce emergency de-
Harnessing Patients’ Voices to Improve Clinical Care

Emergency Department Visits and Probability of Survival Associated with Integrating Patient-Reported Outcomes (PROs) into Cancer Care.

Analysis of a randomized, controlled trial reveals that among 766 patients receiving chemotherapy and assigned either to usual care or to regularly reporting common symptoms over the Internet with automated alerts e-mailed to their nurses for severe or worsening symptoms, the PRO intervention was associated with significantly fewer emergency department visits and improved overall survival, as well as improvements in quality of life. Nurses responded to patients reports of symptoms with clinical actions such as telephone advice and new prescriptions in 76% of cases.5

Yet examination of PROs has not become a widely implemented part of routine care delivery, which would require overcoming three key barriers. The first is technological. The most commonly used EHR vendors in the United States (Allscripts, Cerner, and Epic) have only rudimentary ability to collect PRO data, and it’s generally available only through online patient portals, which most patients don’t use. Ideally, PRO collection would be enabled for patients on their own smart devices in flexible user-configurable formats, perhaps through text messages, automated telephone systems, or downloadable apps. The data could then be imported into the EHR through an interface.

EHR vendors have also not enabled clinicians’ intuitive visualization of PRO data resembling that used for laboratory values, and there is no commonly accepted terminology for PRO data elements. Therefore, even if patients go to the trouble of reporting their own outcomes, the information cannot easily be viewed by health care providers or aggregated across populations.

Ironically, there was greater progress in PRO-interface develop-
ment before EHR systems became so widespread, because hospitals’ initial interest in developing stand-alone PRO systems waned as they began anticipating improvement of this functionality within standard EHR platforms. EHR vendors have thus become a hindrance rather than a facilitator of progress.

All four institutions mentioned above had to create their own electronic PRO platforms, as well as custom interfaces into their EHR systems. Although they have demonstrated the feasibility of that approach, wider implementation would be eased by availability of standardized PRO platforms that could accompany or easily be plugged into the EHR.

The second barrier is reimbursement. The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) recognize the value of collecting PRO data in clinical care but have stopped short of creating strong financial incentives for widespread implementation, largely because of uncertainty about standard implementation approaches. It’s unrealistic to expect most health care organizations to adopt new data systems for collecting PROs, given the expense and logistic changes required. Although CMS currently offers modest per-member-per-month payments for remote monitoring of chronic conditions (Current Procedural Terminology [CPT] code 99091) and chronic care management (CPT code 99490), it has not been prescriptive enough to prompt wide adoption of PRO collection systems. I believe that CMS and the ONC should convene an expert panel to assemble salient evidence and outline a path for creating reimbursement-based incentives in this area. This effort could be informed by a current initiative of the Patient-Centered Outcomes Research Institute (PCORI) and the International Society for Quality of Life Research (ISOQOL) to develop a user’s guide to PRO collection through the EHR, and by prior standards for PRO measurement published by the National Quality Forum.

Dartmouth–Hitchcock, Cincinnati Children’s Hospital, Cleveland Clinic, and Memorial Sloan Kettering have each made a commitment to fund these systems themselves, believing that quality of care and patient satisfaction will be enhanced. But financial incentives for collecting PROs from payers would accelerate broader uptake and would probably benefit payers by reducing emergency department visits and hospitalizations. Accountable care organizations may elect to implement PRO systems because of benefits for symptom management, patient satisfaction, and reduced utilization of emergency services.

The third barrier is the lack of standardized methods for integrating PROs into clinical workflow. Typically, information about patient symptoms and functioning is collected orally at visits, or between visits when patients call their doctor’s office or send messages to a secure portal. PRO collection represents a potential shift in workflow, with patient symptom information coming into the EHR in real time. Providers will need effective approaches for absorbing and responding to this information without disrupting their normal processes, such as processing PRO data through the same provider EHR in-baskets used for patient-portal messages — approaches that may be informed by the PCORI–ISOQOL user’s guide and facilitated by improved technical functionality and financial incentives.

Moreover, broad consensus is needed on which specific outcome assessments should be employed across patients, practitioners, and institutions both to support standardization of clinical workflow procedures and to facilitate consolidation of data from multiple sources. Such standardization can also help minimize the number of PRO questions asked of each patient, particularly for those with multiple chronic diseases who may be seen in more than one clinic. Efforts by the International Consortium for Health Outcomes Measurement to standardize outcomes, including PROs, through consensus are a step in the right direction. The four example institutions developed their own approaches to workflow and outcomes selection, but standardization would avert the need for reinvention at each institution.

Other challenges are surmountable. Standards exist for ensuring data privacy and security, determining the appropriate frequency of data collection, minimizing missing data, and analyzing real-world PRO data. Concerns have been raised about burdening patients with too many questions and about patients’ potential reticence about self-reporting. But research and the example implementation programs have shown that these problems are not substantial when a thoughtful approach is taken.

A common thread in the PRO initiatives implemented to date is that they originated with clinician champions with support from institutional leadership. All these institutions systematically evaluated their patients’ and clinicians’ needs to inform the development of technology-driven approaches for in-
corporeating patients’ voices into routine care delivery.

Beyond clinical care, systematically collected PRO data can be aggregated and linked to other EHR information to support analyses of effectiveness (e.g., which of various interventions controls back pain best?), examinations of quality of care (e.g., do different providers or practices manage post-chemotherapy nausea differently?), and pharmacovigilance (e.g., is a particular drug associated with unexpected symptoms?). Indeed, there is growing national interest in harnessing patient-reported data in all these areas. There is sufficient scientific rationale and understanding of implementation methods to expand collection of PRO data in clinical care. Doing so could turn the rhetoric regarding “patient-centered care” into a reality.

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The Future of Health Care Reform — Section 1332 Waivers and State-Led Reform

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By the beginning of 2016, most major components of reform contained in the Affordable Care Act (ACA) had been implemented, including Medicaid expansion, insurance exchanges, and insurance subsidies. These reforms made substantial inroads in increasing access to care and reducing the uninsured rate. Yet even before the 2016 election, policymakers from both political parties had been calling for further reforms.1 Now, dismantling the ACA will apparently be a central goal in Washington.

Actually repealing and replacing the entire ACA would be a complicated process, even with Republican majorities in both chambers. Gridlock over what a replacement plan would look like and procedural rules may limit what President-elect Donald Trump and Congress can achieve. Already, Republicans and interest groups have expressed concern about the effects of repealing the law in its entirety. The most likely effort will include congressional Republicans passing reconciliation legislation that will repeal a portion of reform while bypassing the threat of a filibuster. This approach, which was vetoed in 2015 by President Barack Obama, would leave some aspects of the ACA intact. One such component is state innovation waivers (Section 1332 waivers), which the Trump administration could use to strengthen state-led reforms or to further undercut the remnants of the ACA.

Section 1332 permits states to waive certain provisions of the ACA, including the individual mandate to obtain health insurance, the employer mandate to provide insurance, and insurance exchanges; it also allows states to modify insurance benefits, cost-sharing requirements, and subsidies. States can finance these reforms by using all federal revenues earmarked for the state under the ACA. Flexibility in reforms, however, cannot be achieved at the expense of meeting the ACA’s broader goals. To ensure compliance, the federal government established “guardrails” to constrain state reforms: states must cover a similar number of people as would be covered by full implementation of the ACA, offer coverage that is no more expensive and no less comprehensive than that of already existing plans, and have no effect on the federal deficit.2

Despite the promise of flexibil-